**INITIAL REVIEW - PRIMARY REVIEWER PRESENTATION TEMPLATE**

This form is to be used by the primary reviewers when making the initial presentation to the board. The form will serve to ensure that the regulatory criteria for approval are presented and considered in the review process and also to bring consistency to the review process between reviewers and across panels. This form is for the summary presentation; specific concerns are to be noted in the IRIS system and addressed AFTER the presentation is completed.

| **IRB Number**:  |
| --- |

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| **PART I – STUDY INTRODUCTION:** | **REVIEWER’S SUMMARY**  |
| In the introduction:* announce the study title, PI and the sponsor,
* provide a brief overview of study (e.g. comment on research question, background information, study design, subject populations)
* provide a brief summary of experience/qualifications of PI/study team
 |  |
| **PART II – PROVIDE AN OVERVIEW OF HOW EACH REGULATORY CRITERION FOR APPROVAL IS ADDRESSED+** | **REVIEWER’S SUMMARY** |
| **Minimization of risks** (e.g. when possible PI is using procedures already being done clinically, PI is using least risky method possible, use of tapering of medications or washout periods, summarize comments from research safety and/or pharmacy, summarize PI comments on application regarding minimization of risks, contract provides for subject injury, adequate resources such as staff, funding, equipment, etc.): |  |
| **Reasonableness of risk** **in relation to potential benefits** (e.g. because there currently is no effective treatment for xx, the risks seem reasonable in relation to the expected benefit of xx which the subject/society may experience):  |  |
| **Appropriateness of subject selection** (e.g. summarize recruitment strategies and material, payments made and structure of such payments, inclusion/exclusion criteria):  |  |
| **Process and documentation of consent / waivers or alterations of consent** (e.g. comment on presence of required elements of consent in the document\*, summarize the process as described in application; e.g. who is providing and obtaining consent, where does process occur, how much time is allotted for consideration, **whether waivers/alterations are requested and if so are the criteria for such met**): |  |
| **Data Monitoring** (e.g. summarize the DSM charter and plans for monitoring, noting frequency, what is being monitored and who is doing it): |  |
| **Protection for Privacy** (e.g. summarize how privacy of individuals will be maintained such as consent and procedures in private setting):  |  |
| **Protections for Confidentiality** (summarize plans to protect confidentiality of data (e.g. use of encryption, codes, passwords, locked files, records in research record only or medical record too etc.):  |  |
| **Protections for vulnerable groups** (comment on vulnerable population to be included and whether the PI has provided adequate justifications on the relevant form, or if justification can be found elsewhere in materials provided, as applicable summarize plans for assent, plans for assessing capacity) |  |
| **Conflicts of Interests** (summarize whether there are any conflicts. If so, summarize the management plan): |  |
| **HIPAA** (summarize how is addressed (e.g. use of HIPAA authorization, noting who disclosures will be made to and if listing of PHI to be disclosed is accurate) |  |
| **Other Considerations** (e.g. if investigator is the sponsor of an IND has s/he satisfied the audit requirements to ensure s/he is prepared to act as sponsor; if funding is from Department of Defense, is Appendix F appropriately completed)  |  |
| **PART III - OVERVIEW OF THE CONCERNS OF THE REVIEWER** | **REVIEWER’S COMMENTS NOTED IN IRIS** |
| Note – Part III will be addressed by review of the comments made on forms and documents in the IRIS system and on the reviewer form in IRIS. |  |

+ The help button on the reviewer form in IRIS contains additional points to consider.

\*Refer to consent checklist in submission packet for complete listing of required elements. Elements are also listed in the help (?) button within IRIS.